

### **Remarks**

Claims 1-20 are pending. Claims 1-12 are directed to a non-elected group and have been withdrawn from consideration. Claims 13 to 20 stand rejected by the Office action (final) dated January 18, 2007. In this amendment, Claims 1 and 13 have been amended.

### **Examiner Interview Summary**

The Examiner provided an Examiner-Initiated Interview Summary via electronic delivery dated February 22, 2007.

In the telephonic interview conducted between the Examiner and Applicants' representative on February 15, 2007, the incomplete rejections under § 112, paragraph 2 were withdrawn as not intended. The "containing" language of claim 16 was discussed which the Examiner interpreted as "comprising" which was further interpreted as extending to the sequences listed therein. The Examiner cited the decision in *In re Crish*, 73 USPQ2d 1364 (Fed. Cir. 2004) as support for this interpretation of claim 16. Applicants representative explained that a "kit" would contain other articles besides the oligonucleotides, e.g., a container that holds the oligonucleotides.

### ***Claim Rejections - 35 USC § 112***

These rejections were withdrawn as unintended in the telephonic interview on February 15, 2007. Therefore, Applicants provide no response to this section of the Office action dated 01/18/2007.

### ***Claim Rejections - 35 USC § 102***

Claim 16 stands rejected as allegedly anticipated by GenBank X53896 (1991) which discloses a 1459 nucleotide sequence that is a partial sequence of *Mycobacterium cookii* 16S rRNA.

This rejection was discussed during the telephonic interview on February 15, 2007, summarized above. The Examiner explained that the term "containing" was interpreted as "comprising" which was further interpreted as extending to the rest of the claim elements, so that claim 16 was interpreted as "A kit *comprising* one or more oligonucleotides *comprising* SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, or SEQ ID NO:24." The Examiner cited the decision in *In re Crish*, 73 USPQ2d 1364 (Fed. Cir. 2004) as support for this interpretation.

Applicants disagree with this interpretation of claim 16 based on the following arguments: (1) claim 16 should be interpreted by using the "plain meaning" of the claim language, consistent with MPEP 2111.01, and (2) the decision in *In re Crish* is distinguishable from the present issue when the plain meaning of claim 16 is used.

Pending claim 16 is drawn to "A kit containing one or more oligonucleotides selected from the group consisting of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, and SEQ ID NO:24."

MPEP 2111.01 states:

Although <claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1369, 70 USPQ2d 1827, 1834 (Fed. Cir. 2004) (The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation >In light of the specification<.). This means that the words of the claim must be given their plain

meaning unless \*\*>the plain meaning is inconsistent with< the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (discussed below); *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004) (Ordinary, simple English words whose meaning is clear and unquestionable, absent any indication that their use in a particular context changes their meaning, are construed to mean exactly what they say. Thus, "heating the resulting batter-coated dough to a temperature in the range of about 400°F to 850°F" required heating the dough, rather than the air inside an oven, to the specified temperature.).

Based on the guidance in MPEP 2111.01, the words of claim 16 must be given their plain meaning unless the plain meaning is inconsistent with the specification. Claim 16 is drawn to a "kit" composition. "Kit" is a simple English word whose meaning was known at the time of the invention to be "a packaged collection of related material" (*Merriam-Webster's Collegiate Dictionary*, 10<sup>th</sup> Ed., p. 644, Merriam-Webster, Inc., Springfield, Mass., 1994). The specification discloses assays and compositions for detecting *Mycobacterium* species present in a biological sample by using combinations of individual oligonucleotides (e.g., primers) and related material such as reagents used in the *in vitro* reactions. Nothing in the rejection of claim 16 points to "kit" being used inconsistent with its plain meaning or use in a particular context that changes its plain meaning. Persons skilled in the art of molecular biology would understand the plain meaning of "kit" and further would understand that oligonucleotides are molecular compounds that cannot be provided in a kit without some packaging, such as a vial or tube to contains the oligonucleotide. "Contain" is a simple English word whose meaning was known at the time of the invention to be "to keep within limits" or to "hold in" (*Id.* at 249). Persons skilled in the art of molecular biology would understand that oligonucleotides specified by SEQ ID numbers would mean specified molecular

compounds, not genetic material that merely shares a relationship to the specified molecular compounds. Therefore, based on the guidance in MPEP 2111.01, the plain meaning of claim 16 is reasonably interpreted as:

"A packaged collection of related material that holds one or more oligonucleotides selected from the group consisting of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, and SEQ ID NO:24."

Pending claim 16 and the above reasonable interpretation of claim 16 differ significantly from the claims at issue in *In re Crish*, which generically read as follows:

"A purified oligonucleotide comprising at least a portion of the nucleotide sequence of SEQ ID NO:1, wherein said portion consists of the nucleotide sequence from XXX to YYY of SEQ ID NO:1, and wherein said portion of the nucleotide sequence of SEQ ID NO:1 has promoter activity."

In the three claims at issue in *In re Crish*, different nucleotide locations within SEQ ID NO:1 were inserted for the "XXX" and "YYY" portions of the generic claim presented herein. The Court of Appeals for the Federal Circuit affirmed the PTO's construction of the *In re Crish* claims as using the open-ended transition term "comprising" and language that required "at least a portion" of SEQ ID NO:1 which implied that the "claims contemplate additional nucleotides" in the claimed purified oligonucleotide. That is, the Court found it to be a reasonable interpretation that a claim directed to a purified oligonucleotide that contains both the terms "comprising" and "consists" where "consists" limits the "said portion" language of the claim to numbered subsequences contained in a specified SEQ ID NO to mean that the claim can include that portion of the SEQ ID NO and other nucleotides.

The interpretation of the claims in *In re Crish* is distinguishable from Applicants' above interpretation of pending claim 16 for the following reasons. First, *Crish* claimed a "purified oligonucleotide" whereas pending claim 16 is drawn to a "kit" that contains

oligonucleotides. Second, Crish claimed a purified oligonucleotide *comprising at least a portion* of a larger specified sequence (SEQ ID NO:1) whereas pending claim 16 claims a kit *containing* one or more specified oligonucleotides "selected from the group consisting of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, and SEQ ID NO:24." Because pending claim 16 is drawn to a kit and does not use the open-ended transition "comprising" but instead uses "containing" which has the plain meaning "to keep within limits" or "hold in" in the context of a "kit" the Court's interpretation of the *In re Crish* claims is inapplicable to pending claim 16.

Claim 16 stands rejected as anticipated by GenBank X53896. To be anticipated, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. *Scripps Clinic & Res. Fndn. v. Genentec, Inc.*, 927 F.2d 1565, 18 U.S.P.Q.2d 1001, 1010, 18 U.S.P.Q.2d 1896 (Fed. Cir. 1991). GenBank X53896 merely teaches a large 16S rRNA sequence from *M. cookii*. GenBank X53896 does not teach a "kit" and does not teach one or more of the selected oligonucleotide sequences selected from the group consisting of SEQ ID NO:21, SEQ ID NO:22, SEQ ID NO:23, and SEQ ID NO:24. Applicants respectfully submit that claim 16 is not anticipated by the cited art and, therefore, request that the rejection of claim 16 under 35 USC § 101 be withdrawn.

#### *Claim Rejections - 35 USC § 103*

Claims 13-20 stand rejected as being unpatentable over McAllister et al. (US 5908744) in view of GenBank X53896 (1991) and further in view of Buck et al. (*BioTechniques*, 1999, 27:528-36). The rejection substantially repeats the rejection of claims 13-15 and 19-20 made in the Office action dated July 28, 2006, based on the same cited references.

The determination of whether an invention would have been obvious under § 103 is a legal conclusion based on underlying findings of fact. *In re Kotzab*, 217 F.3d

1365, 1369 (Fed. Cir. 2000). The underlying factual inquiries include: (1) the scope and content of the prior art, (2) the level of ordinary skill in the prior art, and (3) the differences between the claimed invention and the prior art. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). If all the elements of an invention are found in a combination of prior art references, a proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991) (citing *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988)).

Amended claim 13 is drawn to a composition for amplifying in an *in vitro* amplification reaction a *Mycobacterium* 16S rRNA sequence or a DNA encoding 16S rRNA, comprising a combination of at least one first oligonucleotide and at least one second oligonucleotide, wherein the first oligonucleotide consists of a promoter sequence and a sequence that hybridizes to a *Mycobacterium* 16S rRNA or DNA sequence, and wherein the second oligonucleotide is an oligonucleotide consisting of 19 to 25 bases made up of contiguous bases 1 to 18 of SEQ ID NO:24 and optionally three to seven bases 5' to the contiguous bases 1 to 18 of SEQ ID NO:24 and/or optionally one base 3' to the contiguous bases 1 to 18 of SEQ ID NO:24.

Amended claim 13 clarifies that the at least two oligonucleotides are at least one first oligonucleotide and at least one second oligonucleotide. The structures of the first and second oligonucleotides are described in the two clauses, each following "wherein." That is, amended claim 13 claims a composition that is a combination of oligonucleotides made up of at least one first oligonucleotide that consists of defined elements, and at least one second oligonucleotide that consists of defined elements.

Applicants have previously responded to the rejection under §103 of claims 13-

15 and 19-20 in the amendment filed October 30, 2006, and respectfully refer the Examiner to those remarks for additional details that are not repeated here. Applicants agree that McAllister et al. teach compositions that includes a promoter primer for synthesizing multiple copies of a target nucleic acid which may be a *Mycobacterium* sequence, but do not teach an oligonucleotide in the size range of 19 to 25 bases that contains the contiguous bases 1 to 18 of SEQ ID NO:24, or any of the additional nucleic acids of claims 13 to 20. Applicants also agree that GenBank X53896 teaches a partial 16S rRNA sequence of 1459 bases from *Mycobacterium cookii* that contains nucleotides identical to the selected oligonucleotide sequences identified in this application. The GenBank X53896 reference, however, does not identify or select in any way the oligonucleotide sequences disclosed and claimed in this application. The Examiner, therefore, relied on the Buck et al. reference to allegedly show "the equivalence of primers" to arrive at the obviousness rejections in which "The selection of any oligonucleotide from within this sequence would have been expected to function equivalently with regard to the ability to M. cookii 16S sequences [sic]. One would have been motivated to provide primers that comprised any of the fragments of the GenBank record in order to provide a means for the amplification and detection of this *Mycobacterium* species." (Office action at page 6, lines 8-12.)

Applicants remarks with regard to the Office's reliance on the Buck et al. reference in the earlier §103 rejections of claims 13-15 and 19-20 were discounted in the "Response to Remarks" section of the present Office (at page 17). The "Response to Remarks" also stated that "Arguments of counsel are not found to be persuasive in the absence of a factual showing." The "Response to Remarks" section included many conclusions about the Buck et al. reference that were not supported, e.g., "This is not a flaw in Buck's showing but instead it would be expected...." and "The selection of target sequences that do not contain problematic areas was a routine practice in the technology area...." and "There is no evidence on the record that this [trimmed the raw

data] is an unusual practice, despite applicant's suggestion." To avoid possible "procedural default" (*In re Sun*, 31 U.S.P.Q.2d 1451, 1455 (Fed. Cir. 1993, unpublished)), and to avoid having this assertion "establish[ed]. . . as admitted prior art", Applicants request that the Examiner either provide a reference (37 C.F.R. §1.104(c)(2) and MPEP § 706.02(a)) or an affidavit under 37 C.F.R. § 1.104(d)(2) in support of the positions taken in the "Response to Remarks" section of the Office action dated January 18, 2007.

This amendment is accompanied by a Declaration under Rule 132 made by one of the inventors of this invention. The Declaration describes reasons for not extending the conclusions of the Buck et al. reference to a broad statement that "Buck expressly provides evidence of the equivalence of primers." (Office action at page 5, para. 3.) The Declaration also provides factual evidence that shows that all primers are not equivalent, based on controlled nucleic acid amplification experiments in which tested primers varied by one or two bases from each other. Applicants respectfully request that the Examiner carefully review the Declaration because the information contained therein is not repeated here but is incorporated by reference herein. Based on the information provided in the accompanying Declaration, Applicants submit that the Buck et al. reference cannot be relied on for the general premise that "every primer would have a reasonable expectation of success." (Office action, page 6, line 5.)

The scope and content of the cited prior art does not specify the composition claimed in claim 13 because, even though the level of ordinary skill in the field of molecular biology is quite high, the differences between the claimed invention and the cited prior art are substantial. McAllister et al. do not disclose the particular claimed compositions as the Examiner acknowledged. The GenBank X53896 reference does not identify, select, or otherwise point out the particular oligonucleotide sequences claimed in this application. Absent a suggestion or motivation to arrive at the particular sequences disclosed and claimed in this application, it is unclear how the Buck et al.



reference supplies any missing components that would make the present invention obvious because Buck et al. merely reported a survey of DNA sequencing primers. That is, the cited prior art would not have suggested to those of ordinary skill in molecular biology that they should make the claimed compositions of the present invention (or carry out the process of claim 1). Because all the elements of the claimed invention are not found in a combination of the cited prior art references, Applicants submit that the Examiner has not presented a *prima facie* case of obviousness for claims 13 to 20. Therefore, the analysis under § 103 could stop without consideration of whether the prior art would also have revealed that in making the claimed compositions, those of ordinary skill would have a reasonable expectation of success at arriving at the compositions or using them for amplification of *Mycobacterium* nucleic acid. The Examiner relied on the Buck et al. reference as allegedly showing "the equivalence of primers" which might suggest that a reasonable expectation of success would follow if one skilled in the art were somehow motivated to select the specific sequences disclosed in the present application *without the benefit of Applicants' disclosure*. The Buck et al. reference is responded to in the accompanying Declaration which presents information that shows that the Examiner's conclusion based on the Buck et al. reference is unreliable. Thus, even if the first two references were to suggest selection of alternative primer sequences based on the GenBank X53896 reference, there is no motivation provided in the art to arrive at the functional sequences disclosed and claimed in the present application. Therefore, Applicants submit that a *prima facie* case of obviousness has not been made for claims 13 to 20, and therefore request withdrawal of these rejections.

The rejection of claim 16 cites the GenBank X53896 reference and describes it as "having" each of SEQ ID numbers 21 to 24. This rejection appears to rely on the interpretation of claim 16 discussed above with regard to the rejection under §102. Applicants respectfully refer the Examiner to the reasonable interpretation of the plain

language of claim 16 above. Applying the reasonable interpretation of claim 16 here, Applicants submit that the combination of the cited art under the §103 rejection of claim 16, particularly the combination of the McAllister et al. reference and the partial 16S rRNA sequence of the GenBank reference, would not have suggested the claimed invention of claim 16 to a person of ordinary skill in the art of molecular biology because neither reference directs the skilled person to make the selections of the specified sequences of claim 16. The Buck et al. reference does not cure the deficiencies of the other two cited references. Therefore, the Examiner has not presented a *prima facie* case of obviousness for the kit claims of claims 16 and dependent claims 17 and 18 which describe additional elements contained in the kit. Applicants respectfully submit that those claims are in condition for allowance.

The Office action states that "The sequences set forth in claims 15, 17, 18, 19 and 20 have been addressed." Applicants submit that claims 15, 19 and 20, which depend ultimately from claim 13, are not obvious for the same reasons discussed above for claim 13. Claims 17 and 18 which depend from claim 16 have been discussed above and Applicants submit that they are also in condition for allowance.

Applicants respectfully submit that amended claim 13 and all of claims 14 to 20 are in condition for allowance and request withdrawal of the rejections to the claims and allowance of claims 13 to 20. Applicants have also amended withdrawn claim 1 consistent with the amendments to claim 13 and request rejoinder of claims 1 to 12 if claims 13 to 20 are found allowable.

### **Conclusion**

In view of the foregoing amendments and remarks, the Applicants respectfully submit that the claims are patentable and in condition for allowance. Accordingly, allowance of the application is earnestly solicited. The undersigned has made a good-faith effort to address all the points raised in this Office action and to place the claims in

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AMENDMENT AFTER FINAL REJECTION

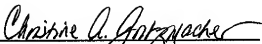
Confirmation No. 6892  
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condition for allowance. However if minor matters remain that could be resolved by telephone interview, the Examiner is invited to contact the undersigned at the number shown below.

No fee is believed due in connection with this response. If Applicants are incorrect, authorization is hereby provided to debit required fees from Deposit Account No. 07-0835 maintained by Gen-Probe Incorporated.

Respectfully Submitted,

Dated: March 19, 2007

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Enclosure: Declaration Under Rule 132